

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ROQUETTE FRÈRES,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 06-540 (***)
	)	
SPI PHARMA, INC. and DRYTEC LTD.,	)	<b>REDACTED</b>
	)	<b>PUBLIC VERSION</b>
Defendants.	)	
_____	)	

**PLAINTIFF'S ANSWERING BRIEF IN OPPOSITION  
TO MOTION TO DISMISS FOR LACK OF PERSONAL JURISDICTION OF  
DEFENDANTS DRYTEC CONTRACT PROCESSING LTD.,  
ANHYDRO U.K. LTD. AND ANHYDRO HOLDING A/S**

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Original Filing Date: July 27, 2007  
Redacted Filing Date: July 31, 2007

i.

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NATURE AND STAGE OF THE PROCEEDING

Defendants Drytec Contract Processing Ltd., Anhydro U.K. Ltd. (formerly "Drytec Ltd.")<sup>1</sup> and Anhydro Holding A/S (collectively "the Drytec Entities") have responded to Roquette Frères' ("Roquette") Second Amended Complaint by moving to dismiss based upon a contention that this Court lacks personal jurisdiction over them. Defendants' contentions are not supported by the facts, and there is ample basis to assert personal jurisdiction over each defendant Drytec Entity.

In its First Amended Complaint (D.I. 9), Roquette alleged that SPI Pharma Inc. and Anhydro U.K. Ltd. infringed Roquette's U.S. Patent No. 5,573,777 ("the '777 patent") through their activities surrounding, *inter alia*, what SPI Pharma Inc. markets in the U.S. as MANNOGEM™ EZ spray-dried mannitol. Anhydro U.K. Ltd. responded on December 6, 2006 by moving to dismiss for lack of personal jurisdiction. (D.I. 19). Following limited jurisdictional discovery, including taking the deposition of Paul C. Kennet, Managing Director of Anhydro U.K. Ltd., on January 16, 2007, Anhydro U.K. Ltd.'s motion was fully briefed to the Court (D.I. 27, 29 and 34). To support its motion to dismiss, Anhydro U.K. Ltd. argued that

[REDACTED]

[REDACTED]

[REDACTED] (D.I. 29, Reply Br. at 6).

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<sup>1</sup> Drytec Ltd., previously named as a defendant, and which previously filed a similar motion to dismiss pursuant to Rule 12(b)(2) states in its brief that it changed its name to Anhydro U.K. Ltd. on January 1, 2007, but effected no other changes to the Company. Defendants assert that Anhydro U.K. Limited has taken the place of Drytec Ltd. as a party defendant. Plaintiff SPI accepts that representation so long as it is understood that both entities are subject to discovery as party defendants and that any relief accorded by this Court applies to both entities. Throughout this Brief, use of either "Anhydro U.K. Ltd." or "Drytec Ltd." refers to both those entities.

2.

On May 21, 2007, Roquette requested leave to amend its pleadings to join Drytec Contract Processing Ltd., as well as Anhydro Holding A/S – the controlling parent company of both Drytec Contract Processing Ltd. and Anhydro U.K. Ltd. (D.I. 48). The Court granted leave on June 25, 2007 (D.I. 65), and Roquette filed its Second Amended Complaint thereafter (D.I. 67).

In its June 25, 2007 Order, anticipating a renewed motion to dismiss, the Court also granted Roquette leave to conduct further jurisdictional discovery from each of the Drytec Entities. (D.I. 65). To that end, Roquette again took the deposition of Paul C. Kennet, representing all three of the Drytec Entities, on July 13, 2007 ("Kennet Deposition II").

In their opening brief (D.I. 71), the Drytec Entities renew the argument that only [REDACTED] and contend that none of the Drytec Entities engaged in infringing activity in Delaware or regularly does or solicits business in Delaware.

As the factual record conclusively will demonstrate, both Anhydro U.K. Ltd. and Drytec Contract Processing Ltd.: (i) maintained a registered agent in Delaware; (ii) contracted with SPI to supply Mannogem<sup>TM</sup> EZ in Delaware; (iii) on multiple occasions shipped Mannogem<sup>TM</sup> EZ to SPI in Delaware; and (iv) solicited and conducted substantial business (and derived substantial revenue) with SPI in Delaware. Moreover, Anhydro Holding A/S is the head of the self-characterized single business entity that includes all of the Drytec Entities.

This is Roquette's Answering Brief in ~~op~~position to the Drytec Entities' motion.

#### SUMMARY OF ARGUMENT

The Drytec Entities have purposefully and continuously over at least a five-year period shipped accused product to SPI in Delaware. Those defendants contracted with SPI

3.

Pharma for the manufacture and supply of accused product, as well as for the sale of key components of a U.S.-based manufacturing installation for Mannogem<sup>TM</sup> EZ. Those defendants have persistently solicited business with, done business with, and derived substantial revenue from SPI Pharma in Delaware involving accused products.

Accordingly, the Drytec Entities' actions satisfy multiple bases for this Court's jurisdiction under Delaware's long-arm statute.

Subjecting the Drytec Entities to the jurisdiction of this Court also comports with due process. The defendants' multiple shipments [REDACTED] constitute purposeful minimum contacts with the State of Delaware. The Drytec Entities could well have expected being haled into court in Delaware to answer for those contacts and acts.

#### STATEMENT OF FACTS

Defendants' motion relies principally upon the Declaration of Paul C. Kennet. He recites the Drytec Entities' lack of an office, employees, real property, and mailing or telephone listing in the State of Delaware (Opening br. at 4, n.3). Mr. Kennet's declaration goes on to assert that neither Anhydro U.K. Limited nor Drytec Contract Processing has a registered agent in Delaware (D.I. 74 at ¶¶ 9, 11, 31 and 33); that they have never transacted business in Delaware (*Id.* at ¶¶ 15 and 37); and that they have never imported Mannogem<sup>TM</sup> EZ into the United States (*Id.* at ¶¶ 6 and 28). Mr. Jensen in his declaration (D.I. 73) reiterates those contentions on behalf of Anhydro Holding A/S.

These statements are demonstrably inaccurate.

As set forth in greater detail herein, the Drytec Entities' assertions of a lack of contact with Delaware are inconsistent with the documents previously produced by them and by

4.

their co-defendant SPI Pharma, and there is more than sufficient cause to maintain jurisdiction over the Drytec Entities in this case.

#### ARGUMENT

This Court determines its own jurisdictional reach under a two-part test. *E.g. ICT Pharm. v. Boehringer Ingelheim Pharm.*, 147 F. Supp. 2d 268, 271 (D. Del. 2001). First, the Court determines whether any part of Delaware's long-arm statute reaches the defendant. *Id.* Delaware Courts construe the long-arm statute "liberally so as to provide jurisdiction to the maximum extent possible." *Id.* (quoting *Boone v. Oy Partek Ab*, 724 A.2d 1150, 1156-57 (Del. Super. 1997)). Then, the Court determines whether imposing jurisdiction comports with constitutional notions of due process. *Id.*

This Court's jurisdiction over each of the Drytec Entities satisfies both prongs of that two-part test.

#### I. THE DELAWARE LONG-ARM STATUTE AUTHORIZES EXERCISING PERSONAL JURISDICTION OVER THE DRYTEC ENTITIES

Defendants' motion is based upon a contention that none of the Drytec Entities engages in infringing activity in Delaware. According to the defendants, [REDACTED]

[REDACTED]

[REDACTED] The defendants further argue that they are not subject to the general jurisdiction provision of Delaware's long-arm statute because "none of the Co-Defendants regularly does or solicits business, engages in any other persistent course of conduct in Delaware or derives substantial revenue from services, or things used or consumed in Delaware." *Id.* Defendants further argue that personal jurisdiction is not permitted under the due process clause of the

5.

Constitution. Finally, defendant Anhydro Holding A/S contends that there are no allegations tying this company in any way to Roquette's allegations of patent infringement.

The Drytec Entities are in error as to each of these contentions, as the factual record conclusively will demonstrate.

In support of their motion to dismiss, defendants rely solely upon the declarations of Paul C. Kennet, Bjarne Henning Jensen, and Colleen M. Blackwell, with their attached exhibits. On two occasions plaintiff has taken the deposition of Paul Kennet, the former Managing Director of Drytec Contract Processing and Drytec Holdings Ltd. and the present Managing Director of Anhydro U.K. Ltd. and Drytec Contract Processing Ltd. As is apparent, these are all closely related entities all doing business from the same address, under the same management, and all commonly controlled and owned.

Defendants first contend that personal jurisdiction may not be found under the Delaware long-arm statute – 10 Del. C. § 3104(c). In his declaration, Mr. Kennet addresses the elements of § 3104(c) and opines that none of the Drytec Entities satisfies any of these elements. (D.I. 74 at ¶¶ 6-20). Satisfaction of any one of these elements would suffice to confirm personal jurisdiction under the Statute. See *Colonial Mortgage Serv. Co. v. Aerenson*, 603 F.Supp. 323, 327 (D.Del. 1985). [REDACTED]

[REDACTED]<sup>2</sup> These statements are demonstrably incorrect.

[REDACTED]

Anhydro U.K. Ltd. has for a number of years appointed and maintained an agent in the State of

<sup>2</sup> Where appropriate, Roquette cites a document's numbered page (x) and lines (yy) as "x:yy."



Delaware – this agent being none other than SPI Pharma itself. [REDACTED]

[REDACTED] Moreover, the appointment of SPI as agent was made for the specific purpose of allowing mannitol powder, transformed and manufactured into Mannogem™ EZ by the Drytec Entities, to be delivered to SPI Pharma for sale within the United States. Mannogem™ EZ is a pharmaceutical product, and it is a requirement of the U.S. Food and Drug Administration that a foreign manufacturer of a pharmaceutical product appoint and maintain a statutory agent in the United States in connection with the import and sale of the product. 21 U.S.C. § 360(i)(1); 21 C.F.R. § 207.40(c). Of course, this is the very product which is accused as infringing Roquette's patent-in-suit.

[REDACTED]

[REDACTED]

[REDACTED] Drytec Contract Processing also designated SPI as its U.S. agent, also for the specific purpose of foreign manufacture and import of Mannogem™ EZ. [REDACTED]

[REDACTED]

7.

Thus, defendants' crucial contention made by Mr. Kennet in his declaration (*Id.* at ¶¶ 9 and 11) [REDACTED] that no Drytec Entity has ever had an agent in the State of Delaware indisputably is incorrect. It is significant that the agent was appointed for the specific purpose of enabling the Drytec Entities to deliver Mannogem™ EZ for sale in the United States, including Delaware.

Mr. Kennet further denied, both in his declaration and in his deposition testimony, that any Drytec Entity satisfies subparagraph 2 of § 3104(c), which confers personal jurisdiction over a person who in person or through an agent "contracts to supply services or things in this State." Attached as Exhibit C hereto are a series of documents which evidence [REDACTED]

[REDACTED] In other words, the infringing product was being sent by both of these defendants to three different SPI facilities in Delaware on a routine and continuing basis.<sup>3</sup>

This multi-year series of Delaware-oriented business transactions was not coincidental. [REDACTED]

<sup>3</sup> As noted, many of these shipments of the accused Mannogem™ EZ were made by Anhydro U.K. Ltd., which has been attempting to disassociate itself from this lawsuit with the incorrect contention that [REDACTED]

[REDACTED] The documents in Exhibit A are additional proof as to the inaccuracy of Anhydro U.K. Ltd.'s professed non-involvement.

8.

[REDACTED]<sup>4</sup> (D.I. 74, Declaration of Paul Kennet, Exh. D at  
D 000038, ¶ 3(a)).

[REDACTED] (See Exh. D hereto). [REDACTED]

[REDACTED]

[REDACTED]

Thus, even apart from the fact that Anhydro U.K. Ltd. and Drytec Contract Processing maintained SPI Pharma as their registered U.S. agent in Delaware, these regular and direct shipments of Mannogem<sup>TM</sup> EZ by those defendants to SPI in Delaware are sufficient to invoke this Court's specific jurisdiction under the "transacting business" provision of § 3104(c)(1). *See Philips Electronic North America Corp. v. Contec Corp.*, Civ. A. 02-123-KAJ,

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4

[REDACTED]

2004 WL 503602, at \*5 (D. Del. March 11, 2004) (finding specific personal jurisdiction under § 3104(c)(1) over nonresident manufacturer of imported infringing products).<sup>5</sup>

Under the "contracts" provision of § 3104(c)(2), those defendants' agreements with SPI to manufacture Mannogem™ EZ and to regularly deliver [REDACTED] [REDACTED] are also sufficient to invoke this Court's specific jurisdiction.

It also appears indisputable that the Drytec Entities' continuing and contractual shipments of Mannogem™ EZ into the State of Delaware satisfy element (3) of § 3104(c). Section 3104(c)(3) provides for personal jurisdiction when a non-resident or its agent causes a tortious injury in Delaware by a Delaware act or omission. *Applied Biosystems, Inc. v. Cruachem Ltd.*, 772 F. Supp. 1458, 1467 (D. Del. 1991). In a patent infringement case, the legal situs of the tortious injury is any location where the infringing activity impacts the patentee's interest. *Beverly Hills Fan Co. v. Royal Sovereign Corp.*, 21 F.3d 1558, 1571 (Fed. Cir. 1994).

[REDACTED]

[REDACTED]

<sup>5</sup> This unreported case was appended as Exhibit 8 to Roquette's previous Answering Brief (D.I. 27).

<sup>6</sup> The Drytec Entities in their opening brief are silent regarding their activities prior to October 1, 2003. [REDACTED]

10.

For that purpose, J.M. Pope – then Managing Director of Anhydro U.K. Ltd. and Drytec Contract Processing – personally traveled to Delaware to meet SPI's executives regarding their developing business plans for the manufacture of spray-dried mannitol. (See Exh. E at 3 and 8). Thus, it is clear that the contracts with Delaware-based SPI Pharma originated from the Drytec Entities' affirmative Delaware acts.

Likewise, element (4) of § 3104(c) which includes causation of:

tortious injury in the State or outside of the State by an act or omission outside the State if he regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State

indisputably is satisfied by the Drytec Entities' conduct. Under element (4), the tortious act or omission may occur outside the State of Delaware if the defendant regularly “does or solicits business” or “engages in any other persistent course of conduct in the State” or “derives substantial revenue from services or things used in the State.” Defendants’ acts satisfy each of these disjunctive requirements. The five-year course of conduct, including manufacture of Mannogem™ EZ for delivery to SPI, clearly constitutes the regular solicitation of business in the State of Delaware as well as a persistent course of conduct in the State. Moreover, the Drytec Entities unquestionably have derived substantial revenue from their long-term business dealings with SPI Pharma. (See, e.g., Exh. F showing more than [REDACTED] income derived in just one instance of three-weeks of manufacture).

The Drytec Entities have also derived substantial revenue from their sale of key spray-drying equipment (designed for the manufacture of Mannogem™ EZ) to SPI Pharma.

[REDACTED]

11.

[REDACTED]

The defendants contend, despite all of the foregoing business activities undertaken by both Anhydro U.K. Ltd. and Drytec Contract Processing with SPI Pharma, that the parent company Anhydro Holding A/S played no role. (Opening br. at 6). Contrary to defendants' contention, it is clear that [REDACTED]

[REDACTED] (See  
Exh. G). [REDACTED]

[REDACTED]

Consistent with that [REDACTED] requirement, Anhydro Holding A/S announced via the consolidated website for all the Anhydro companies:

As of January 1, 2007, all of the member companies of the Anhydro Group as well as our regional sales companies assumed the Anhydro name and became part of one single entity known as Anhydro. (Exh. H).

Anhydro Holding A/S's [REDACTED]

in addition to its self-proclaimed status as head of the "one single entity" encompassing all of the Drytec Entities, is sufficient to establish personal jurisdiction over it in this case.

## II. EXERCISING JURISDICTION COMPORTS WITH DUE PROCESS

The exercise of personal jurisdiction satisfies due process when the defendant engaged in "certain minimum contacts . . . such that the maintenance of the suit does not offend 'traditional notions of fair play and substantial justice.'" *Int'l Shoe Co. v. Washington*, 326 U.S.

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<sup>7</sup> See Kennet Deposition II, Exh. A hereto at 47:20 to 48:13.

310, 316 (1945) (quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940)). Minimum contacts are established when the defendant "purposefully avails itself of the privilege of conducting activities within the forum State" *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985) (quoting *Hanson v. Denckla*, 357 U.S. 235, 253 (1958)), such that the defendant could have anticipated being haled into the courts of the forum State, *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 291-92 (1980). Courts may also consider the relative burden imposed on the foreign defendant and the interests of the plaintiff and the forum State. *Asahi Metal Indus. v. Superior Court of California*, 480 U.S. 102, 114 (1987).

The Drytec Entities' documented conduct more than satisfies the requisite minimum contacts. These defendants purposefully availed themselves of the privileges and laws of Delaware when they designated Delaware-based SPI as their registered agent, when they sent their then-Managing Director to SPI's offices in Delaware, when they contracted with Delaware-based SPI, and when they arranged shipments of accused product to, the Delaware-based SPI company. Any of the Drytec Entities' direct and long-term business relationships with SPI would have given them advanced notice that they could anticipate being haled into the Delaware courts. Finally, any inconvenience imposed on the Drytec Entities in having to return to Delaware for this case is slight in comparison to the countervailing interests of Roquette, in defending against infringement of its patent that occurred in this State, and the interests of Delaware in policing its resident corporations and efficiently considering Roquette's claim that arises from the concerted actions of SPI and the Drytec Entities.

The Drytec Entities' argument that their contacts with Delaware "[do] not rise to the level of continuous and systematic" is untenable in light of their documented ongoing business relationship with SPI in Delaware, including the regular shipment of Mannogem<sup>TM</sup> EZ

samples to Delaware, for more than 5 years. Their argument that all of the Drytec Entities' activities occurred in the U.K. is also untenable in light of their documented shipments of Mannogem<sup>TM</sup> EZ to Delaware and the fact that their [REDACTED] Delaware to negotiate the contracts. The Drytec Entities' direct shipments to SPI in Delaware directly infringed Roquette's patent-in-suit. The Drytec Entities' also contributorily infringed by selling in the U.S. key components needed for SPI's own facility for manufacturing Mannogem<sup>TM</sup> EZ. Moreover, as the documents make clear, although the physical location of SPI Delaware's spray-drying plant ultimately was Michigan, it is undeniable that consideration and approval of the construction of the plant, review and approval of its design parameters, and financing and payment for the plant all were accomplished by SPI Delaware. Indeed, documents produced by SPI indicate that [REDACTED]

[REDACTED]

[REDACTED]

Moreover, even the Drytec Entities' purely extraterritorial acts in this case support Roquette's claims regarding induced infringement. See *Wing Shing Products (BVI), Ltd. v. Simatelex Manufactory Co., Ltd.*, 479 F. Supp. 2d 388, 410 (S.D.N.Y. 2007) (holding that even purely extraterritorial acts can give rise to liability for induced infringement). The Drytec Entities' purposeful acts, targeted at SPI Pharma in Delaware, thus give rise to three separate bases for Roquette's allegations of patent infringement. Whatever consequential costs that the Drytec Entities will incur in returning to Delaware to answer for those acts do not offend traditional notions of fair play and substantial justice.



CONCLUSION

For the foregoing reasons, Plaintiff Roquette respectfully requests that the Drytec Entities' motion to dismiss for lack of personal jurisdiction be denied.

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July 27, 2007  
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## **EXHIBIT A**

**REDACTED**

**IN ITS ENTIRETY**

## **EXHIBIT B**

**REDACTED**

**IN ITS ENTIRETY**

## **EXHIBIT C**

**REDACTED**

**IN ITS ENTIRETY**

## **EXHIBIT D**



**REDACTED**

**IN ITS ENTIRETY**

## **EXHIBIT E**

**REDACTED**

**IN ITS ENTIRETY**

## **EXHIBIT F**

**REDACTED**

**IN ITS ENTIRETY**

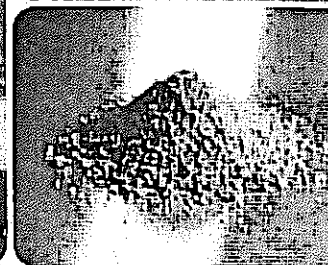
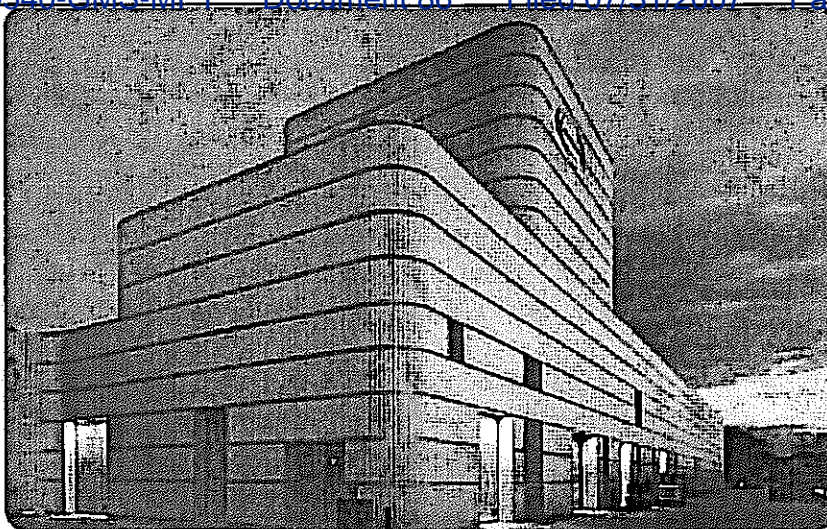
## **EXHIBIT G**

**REDACTED**

**IN ITS ENTIRETY**

## **EXHIBIT H**





## The new Anhydro

January 31, 2007

As of January 1, 2007, all of the member companies of the Anhydro Group as well as our regional sales companies assumed the Anhydro name and became part of one single entity known as Anhydro. By uniting under a single name, we will underline the reach and strength of Anhydro as a global supplier who can focus the sum of its worldwide resources on the individual needs of its customers.

This re-branding process is supported by our new company logo and a new web site with a fresh, dynamic design and strong customer focus.

### Centres of Excellence

Re-branding is also about the way we see ourselves and the way we work together to provide even faster and more effective solutions to our customers all over the world. It is about leveraging the synergies within the new organization, not only in the solutions and processes we develop but also in the way we work.

Our new customer-focused organization is based on three Centres of Excellence - Dairy & Food, Starch & Ethanol, and Industrial & Pharma. Each of these centres unites the relevant technologies, expertise and competences within the organization, directing them specifically at customer needs in the industries they serve.

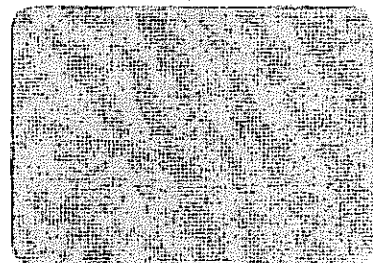
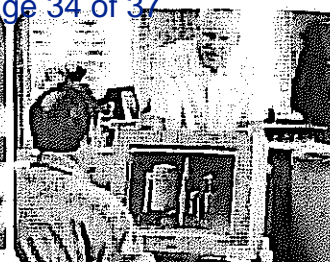
Supporting these three Centres of Excellence is a fourth Centre of Excellence, Parts & Service, that provides customer service to all of our customers around the world.

### Platform for growth

2006 was a year in which we experienced significant growth driven by increased market awareness of the benefits we have to offer in terms of solutions and expertise. While our new brand will reinforce this awareness, our new organization will deliver the promise in terms of our own awareness of and focus on the individual needs of our customers.

Adapting to major changes always presents challenges. I am convinced, however, that our new identity and organization are the platform we need to launch Anhydro into the future and that we stand on the threshold of a new era for Anhydro as a company and as a successful and inspiring place to work.

Allan Jørgensen  
President & CEO



## Contact Us

Anhydro has companies in Europe, the USA, South America and Asia as well as sales offices, agents and distributors all over the world.

There is someone at Anhydro who can help you and is no farther away than an e-mail or phone call. You may also contact the Anhydro sales office agent or distributor nearest to you.

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# **EXHIBIT I**

**REDACTED**

**IN ITS ENTIRETY**

**CERTIFICATE OF SERVICE**

I, the undersigned, hereby certify that on July 31, 2007 I electronically filed the foregoing with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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